II. REMARKS

By the present amendment, independent claims 21, 31, 36 and 37 have been amended to rearrange limitations, which has no further limiting effect on the scope of these claims. In addition, claims 21, 31, 36 and 37 have been amended to recite "mounting the bar of the stud in a fistula in a wearer's tongue or in the wearer's lip" as supported by Figure 11 and on page 6, lines 6-8, of the application as originally filed.

The present amendment adds no new matter to the above-captioned application.

A. The Invention

The present invention pertains broadly to a method for dispensing a substance into a mouth, such as could be used to dispense a breath freshener, a flavoring agent, a medication, or a combination of these substances. In one embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 21. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 31. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 36. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 37.

Various other embodiments, in accordance with the present invention, are recited in the dependent claims. All of the embodiments, in accordance with the present invention, provide the advantage of using a "mouth and tongue stud" to dispense a substance into a wearer's mouth.

B. The Rejection

Claims 21, 31 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Denney et al. (U.S. Patent 6,047,209, hereafter, the "Denney Patent"). Claims 22-30 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Denny Patent.

Applicant respectfully traverses the rejection and requests reconsideration of the application for the following reasons.

C. Applicant's Arguments

Anticipation under 35 U.S.C. § 102 requires showing the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984). A prima facie case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation to combine the references to produce the claimed invention. In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992); In re Vaeck, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

In the present case, the Section 102 rejection is untenable and must be withdrawn because the Denny Patent fails to teach, or even suggest, a "method for dispensing a substance into a mouth" that includes the step of "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud... wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar" and wherein "the first end member removably attaches to the one end of the bar" and "mounting the bar of the stud in a fistula..." as recited in independent claims 21, 31, 36 and 37. For the same reason, the Section 103 rejection is untenable and must be withdrawn.

i. The Denny Patent

U.S. Patent 6,047,209, the Denny Patent, teaches a "method and apparatus for maintenance of

pierced orifices" for injecting fluid into a pierced body orifice (See Abstract). Specifically, the Denny Patent teaches a "needle" (103) as shown in Figure 3, or a "ring" (401) as shown in Figure 4. Both of these Figures are reproduced below.

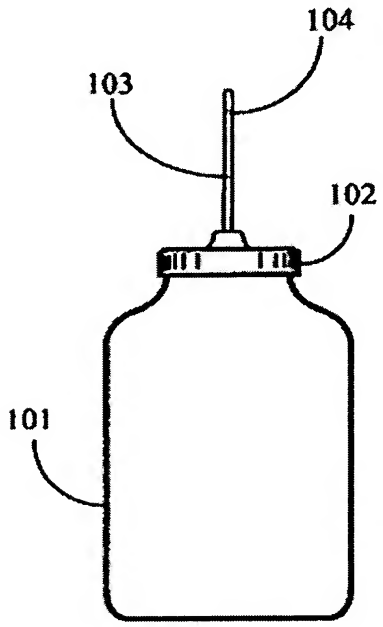

Fig. 1

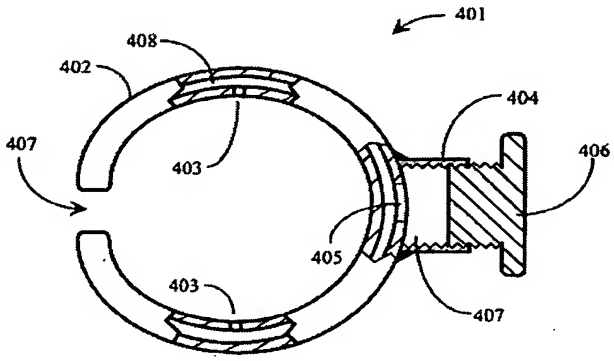

Fig. 4

Neither apparatus is a "mouth and tongue stud" because neither needle (103) or ring (401) include structure that would allow them to remain in the tongue or other piercing that involves the mouth. Therefore, the Examiner's Section 102 rejection is facially flawed because the Denny Patent does not teach, or even suggest, "providing a mouth and tongue stud including means for dispensing a substance..." as recited in independent claims 21, 31, 36 and 37 of the present application. Furthermore, the Denny Patent does not teach, or suggest, "mounting the bar of the stud in a fistula..." as recited in independent claims 21, 31, 36 and 37.

Those skilled in the art would realize that the mouth is a very active place so jewelry used in the mouth must have appropriate structure for securing it in place; otherwise, the jewelry will fall out of place and be swallowed or aspirated. The production of saliva, which is a lubricant, makes this problem even more acute. A reasonable person skilled in the art would not place a needle (103), or an

unsecurable ring (401), in the mouth of a wearer to maintain a "pierced orifice" because of the hazard created by placing unsecurable objects in the mouth. In other words, the fact that the needle (103) and the ring (401) taught by the Denny Patent does not have structure to secure it in place in a fistula is evidence that these devices are not a "mouth and tongue stud" as recited by the independent claims.

In addition, the Denny Patent describes placing the needle (103) in a "pieced orifice" having an interior (302), but the use of hydrogen peroxide, soap and water, and topical antibiotics would reasonably suggest to one skilled in the art that Denney teaches a device for application to "any pierced orifice **on** the body" (col. 3, lines 28-54, and Figure 3), which would not include piercings involving the mouth. There is nothing in the Denny Patent that teaches, or even suggests, that the method would apply to intraoral piercings.

However, this is not the only deficiency in the teachings of the Denny Patent demonstrating that Denny does not teach a "mouth and tongue stud" as recited in the claims. The Denny Patent also does not teach, or suggest, that (a) "the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar" and (b) "the first end member removably attaches to the one end of the bar" as recited in independent claims 21, 31, 36 and 36.

As shown in Figure 1 of the Denny Patent, the needle (103) has no "first end member" and no "second end member" as recited in claims 21, 31, 36 and 37. This fact is even more evident from Figure 3 of the Denny Patent, which is reproduced below.

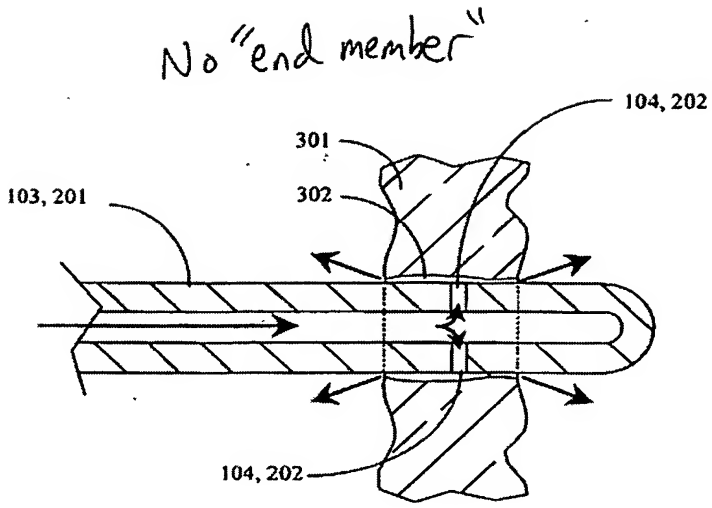

Figure 3 (modified) of the Denny Patent

I have pointed out and clearly shown that the Denny Patent does not teach, or even suggest, devices that are mouth and tongue studs, or that could even be reasonably used in the oral cavity of a wearer. Therefore, the Denney Patent cannot teach, or even suggest, the subject matter of claims 21, 31, 36 and 37 because the reference does not disclose the step of "providing a mouth and tongue stud including a means for dispensing a substance."

The Federal Circuit has ruled that the United States Patent and Trademark Office (USPTO) must give a fair reading to what a reference teaches as a whole. In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In the present case, the Denny Patent plainly teaches a device that includes a needle (103) or a ring (401). These are two separate embodiments, yet the Examiner incorrectly refers to these different embodiments as if their parts are interchangeable (Office Action, dated June 14, 2006, at 2, lines 13, to at 3, line 4; and Office Action, dated March 2, 2006, at 3, lines 7-15).

In addition, the Examiner erroneously contends that base (404) of the embodiment shown in Figure 4 is a "bar having ends" in accordance with a "mouth and tongue stud" as recited in the instant claims. The Examiner's contention is flawed because the Denny Patent does not teach, or suggest, that the base (404) is used to mount the ring (401) to a pieced tongue or lip. On the contrary, the Denny Patent explicitly teaches that it is the ring body (402), and not the base (404), that is placed through the orifice of a piercing (col. 4, lines 59-66). Therefore, the Denny Patent does not teach, or even suggest,

"mounting the bar of the stud in a fistula in a wearer's tongue or in the wearer's lip" as recited in independent claims 21, 31, 36 and 37.

Furthermore, a person of ordinary skill in the art would immediately realize that the base (404) of Denny's ring (401) is not a "bar having ends" of a "mouth and tongue stud," which is used to mount the stud to the wearer by "mounting the bar of the stud in a fistula in a wearer's tongue or in the wearer's lip." As shown in Figures 4 and 5 of the Denny Patent, the base (404) is a short structure. A person of ordinary skill in the art would immediately realize that such a short structure could not be used as the "bar" of a "mouth and tongue stud" because the "bar" must be sufficiently long; otherwise, the "stud" will become embedded in the tongue or lip of the wearer which is an undesirable complication of "mouth and tongue stud" use (See 43 AUSTRALIAN DENTAL JOURNAL 387, 388 (1998)(of record)).

A person of ordinary skill in the art would also instantly realize that the base (404) taught by the Denny Patent is too short and fat for use as the "bar" of a "mouth and tongue stud." Based on a conventional length of 12-15 mm for the bar of a tongue barbell, for example, if the base (404) were made this length, it would also have a width that is about the same (See Figure 4 of the Denny Patent, and 43 AUSTRALIAN DENTAL JOURNAL at 388). This would be an exceptionally wide "bar." In addition, the ring body (402) would be about four times larger as shown by Figure 4 of Denny, or about 48-60 mm, which is way too large a structure for use in a wearer's mouth.

In sum, the Examiner has not established a prima facie case of anticipation against the claims of the instant application because the Denny Patent does not teach, or even suggest, a "mouth and tongue stud" as recited in independent claims 21, 31, 36 and 37. Furthermore, the Denny Patent does not teach, or even suggest, "mounting the bar of the stud in a fistula formed in a wearer's tongue or in the wearer's lip" as recited by independent claims 21 and 31 and, "mounting the bar of the stud in a fistula in a part of wearer's mouth" as recited by independent claims 36 and 37 of the present application.

ii. The Section 103 Rejection

A proper rejection under Section 103 further requires showing (1) that the prior art would have suggested to a person of ordinary skill in the art that they should make the claimed device or carry out the claimed process, (2) that the prior art would have revealed to a person of ordinary skill in the art that in so making or doing, there would have been a reasonable expectation of success, and (3) both the suggestion and the reasonable expectation of success must be found in the prior art and not in the applicants' disclosure. In re Vaeck, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

In this case, the Examiner concedes that the Denny Patent does not teach, or suggest, that "the substance comprises a breath freshener or a flavoring agent or a breath freshener mixed with a flavoring agent" (Office Action, dated June 14, 2006, at 4, lines 11-13; and Office Action, dated March 2, 2006, at 4, lines 6-8). However, the Examiner contends that it would be obvious for the substance to comprise "a breath freshener or flavoring agent or a breath freshener with a flavoring agent or a medication mixed with a breath freshener or a medicine with a flavoring agent since the medication will have a flavor to it whether the flavor pleasantly appeals to user or not it still has a flavor to it and as for the breath freshener, the antibiotic medication will kill also the bacteria that causes bad breath and therefore work as a breath freshener" (Office Action, dated June 14, 2006, at 4, 14-20).

The Examiner's contention is flawed on multiple grounds. First, during examination, the claims should be given their broadest reasonable interpretation consistent with the specification, In re Hyatt, 54 U.S.P.Q.2d 1664, 1667 (Fed. Cir. 2000); however, this does not give the Examiner license to give an unreasonable interpretation to the claims. In this case, a person of ordinary skill in the art would understand from my original specification, at 6, lines 12-13, that a "flavoring agent" is something that improves the taste of the substance. It is unreasonable for the Examiner to construe the term "flavoring agent" to include simply anything that has a "flavor," including bad tasting medications.

Second, the Examiner's contention that an "antibiotic medication will kill also the bacteria that causes bad breath and therefore work as a breath freshener" is flawed because the Examiner has not provided any evidence in support of this position. I remind the Examiner of her obligation under the

Administrative Procedure Act to show the evidence on which her findings are based. In re Lee, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002). The Examiner cannot simply speculate or misread what the prior art teaches; instead, the Examiner must provide "substantial evidence support" for any Section 103 rejection. In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). In this case, not only has the Examiner failed to provide "substantial evidence support" for the contention that antibiotics are "breath fresheners" because they kill bacteria, I provide evidence to refute the Examiner's position. Filed herewith are copies of 12 CLINICAL EVIDENCE CONCISE 367, 367-8 (2004) and 15 CLINICAL EVIDENCE CONCISE 472-3 (2006), which provide articles pertaining to physiological halitosis and the effective treatments used for this condition. Antibiotics are not listed as an effective treatment for physiological halitosis. Consequently, the Examiner should withdraw the Section 103 rejection standing against claims 22, 24, 25, 27 and 36 because the Section 103 rejection lacks "substantial evidence support."

The Denny Patent also does not teach, or suggest, that "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" as recited by claims 28-30. As admitted by the Examiner, the Denny Patent teaches that the substance is disposed "by injecting the substance into the piercing" and that the Denny Patent does not teach or suggest "the substance is disposed by dissolving the substance over time in the wearer's saliva" (Office Action, June 14, 2006, at 4, lines 21-23). Despite this admission, the Examiner contends that it would have been obvious for the substance, after it has been injected into the piercing, to also dissolve over time in the wearer's saliva once in the mouth and that such a condition would meet the claimed limitation (Office Action, dated June 14, 2006, at 4, line 22, to at 5, line 3). I disagree with the Examiner's conclusion because the Examiner has misread the claim and the teachings of the Denny Patent.

According to claims 28-30, the "substance is dispensed into the wearer's mouth by dissolving the substance...in the wearer's saliva." The Denny Patent explicitly teaches that its apparatus is "for injecting fluid into a pierced body orifice" (See Abstract, emphasis added). The Denny Patent teaches that when the bottle (101) is squeezed, fluid is sent through the needle openings, such as shown in

Figure 3 (col. 3, lines 43-45). With respect to the embodiment of Figure 4 of the Denny Patent, fluid is "manually expressed" into the orifice of the pierced orifice when the knob or plunger (406) is turned (col. 4, lines 52-67). I contend that, first, the Denny Patent does not teach, or suggest, placing the needle (103) or ring (401) in the wearer's mouth. Therefore, the Denny Patent does not teach, or suggest, that the "substance is dispensed into the wearer's mouth by dissolving the substance...in the wearer's saliva" as recited by claims 28-30.

Second, even if the needle (103) or the ring (401) were placed in the wearer's mouth (which I contend is not taught by Denny and would not be a reasonable thing to do), the Denny Patent teaches that the substance contained in either Denny's bottle (101) or ring (401) is injected into the orifice of the piercing by squeezing the bottle (101) or by turning the knob (406), respectively, so that the substance is "dispensed." Therefore, any subsequent dissolving of the substance that occurs after its injection into the mouth is not relevant as the Examiner contends. In other words, the Denny Patent teaches that the substance is "dispensed" by injection and not that the substance is "dispensed into the wearer's mouth by dissolving the substance...in the wearer's saliva." If Denny's needle (103) or ring (401) were placed in a wearer's mouth (which I contend is not a reasonable thing to do), any dissolving of the substance in the wearer's saliva occurs after the substance has already been "dispensed into the wearer's mouth" by injection.

All of the methods of "dispensing" taught by the Denny Patent involve injecting fluid through a needle (103) or ring body (402). On the other hand, in accordance with embodiments of the present invention recited by claims 28-30, the substance "is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva." The Denny Patent does not teach, or suggest, this limitation of the claimed invention.

For all of the above reasons, the Examiner has not established a prima facie case of obviousness, against the subject matter of claims 21-31, 36 and 37.

III. CONCLUSION

The Examiner has failed to establish either a prima facie case of anticipation or a prima facie case of obviousness against claims 21-31, 36 and 37 of the above-captioned application because the Denny Patent does not teach, or even suggest, the step of (i) "providing a mouth and tongue stud wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar; and the first end member removably attaches to the one end of the bar" and (ii) "mounting the bar of the stud in the fistula..." as recited in independent claims 21, 31, 36 and 37.

For all of the above reasons, claims 21-31, 36 and 37 are in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed applicant.

Respectfully submitted,

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Team and Adviso

Halitosis

Search date December 2003

Bazian Ltd

What are the effects of treatments in people with physiological halitosis?

LIKELY TO BE BENEFICIAL

Regular-use mouthwash

Two RCTs found that regular use of a mouthwash (one mouthwash containing cetylpyridinium chloride plus chlorhexidine plus zinc lactate; the other mouthwash containing cetylpyridinium chloride) reduced breath odour at 2–4 weeks compared with placebo.

Single-use mouthwash (short term benefit only)

Four small RCTs found limited evidence that single-use mouthwash reduced odour unpleasantness and odour intensity between 1–8 hours after use compared with distilled water, saline rinse, or no treatment. One of these RCTs found no significant difference between single-use mouthwash and distilled water in odour unpleasantness or odour intensity after 24 hours.

UNKNOWN EFFECTIVENESS

Artificial saliva; sugar free chewing gums; tongue cleaning, brushing, or scraping; zinc toothpastes

We found no RCTs on the effects of these interventions.

DEFINITION Halitosis is an unpleasant odour emitted from the mouth. It may be caused by oral conditions including poor oral hygiene and periodontal disease or extra oral conditions such as chronic sinusitis and bronchiectasis.[1,2] In this chapter, we deal only with physiological halitosis, that is, confirmed persistent bad breath in the absence of systemic, periodontal, or gum disease. We have excluded halitosis due to underlying disease, which would require disease specific treatment, pseudo-halitosis (in people who believe they have bad breath but whose breath is not considered malodourous by others), and artificially induced halitosis (e.g. in studies requiring people to stop brushing their teeth). This topic is only applicable, therefore, to people in whom underlying causes have been ruled out, and in whom pseudo-halitosis has been excluded. There is no consensus regarding duration of bad breath for diagnosis of halitosis, although the standard organoleptic test G for bad breath involves smelling the breath on at least two or three different days.[1]

INCIDENCE/ PREVALENCE We found no reliable estimate of prevalence, although several studies report the population prevalence of halitosis (physiological or because of underlying disease) to be about 50%.[1, 3–5] One cross-sectional study of 491 people found that about 5% of people with halitosis have pseudo-halitosis and about 40% of people with halitosis have physiological bad breath not due to underlying disease.[6] We found no reliable data about age or sex distribution of physiological halitosis. ▶

Halitosis

AETIOLOGY/ RISK FACTORS We found no reliable data about risk factors for physiological bad breath. Mass spectrometric and gas chromatographic analysis of expelled air from the mouth of people with any type of halitosis have shown that the main malodourants are volatile sulphur compounds including hydrogen sulphide, methyl mercaptan, and dimethyl suphide.[7,8]

PROGNOSIS We found no evidence on the prognosis of halitosis.

Please refer to CD-ROM for full text and references.

What are the effects of wisdom teeth?

LIKELY TO BE INEFFECTIVE

Extraction of asymptomatic

One systematic review of two improves outcomes compare causes permanent numbnes

DEFINITION Wisdom teeth are erupt between the in the age of er completely impact tion, or abnormal because of pain a

INCIDENCE/ PREVALENCE Third molar impact years have at leas impacted third mo procedure perform about 4/1000 peo 10 inpatient and maxillofacial surge teeth.[3]

AETIOLOGY/ RISK FACTORS Impacted wisdom childhood might in

PROGNOSIS Impacted wisdom destroying adjacen wisdom teeth alle function. We found people with asymp

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Halitosis

Search date December 2004

Crispian Scully CBE and Stephen Porter

What are the effects of treatments in people with physiological halitosis?

LIKELY TO BE BENEFICIAL

Regular-use mouthwash

Two RCTs found that regular use of a mouthwash (one mouthwash containing chlorhexidine plus cetylpyridinium chloride plus zinc lactate, the other mouthwash containing cetylpyridinium chloride) reduced breath odour at 2–4 weeks compared with placebo.

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Three small RCTs found limited evidence that single-use mouthwash reduced odour unpleasantness and odour intensity between 1–8 hours after use compared with distilled water or placebo. One of these RCTs found no significant difference between single-use mouthwash and distilled water in odour unpleasantness or odour intensity after 24 hours.

UNKNOWN EFFECTIVENESS

Artificial saliva

We found no systematic review or RCTs on the effects of artificial saliva.

Sugar-free chewing gums

We found no systematic review or RCTs on the effects of sugar-free chewing gum.

Tongue cleaning, brushing, or scraping

We found no RCTs on the effects of tongue cleaning, brushing, or scraping.

Zinc toothpastes

We found no systematic review or RCTs on the effects of zinc toothpaste.

DEFINITION

Halitosis is an unpleasant odour emitted from the mouth. It may be caused by oral conditions including poor oral hygiene, oral and periodontal disease,[1,2] or conditions such as chronic sinusitis, tonsillitis and bronchiectasis. In this chapter, we deal only with physiological halitosis, that is, confirmed persistent bad breath in the absence of systemic, oral or periodontal, disease. We have excluded halitosis due to underlying systemic disease, which would require disease specific treatment, pseudo-halitosis (in people who believe they have bad breath but whose breath is not considered malodourous by others), and artificially induced halitosis (e.g. in studies requiring people to stop brushing their teeth). This topic is only applicable, therefore, to people in whom such underlying causes have been ruled out, and in whom pseudo-halitosis has been excluded. There is no consensus regarding duration of bad breath for diagnosis of halitosis, although the standard organoleptic test for bad breath involves smelling the breath on at least two or three different days.[1]

INCIDENCE/ PREVALENCE

We found no reliable estimate of prevalence, although several studies report the population prevalence of halitosis (physiological or because of underlying disease) to be about 50%.[1,3-5] One cross-sectional study of 491 people found that about 5% of people with halitosis have pseudo-halitosis and about 40% of people with halitosis have physiological bad breath not due to underlying disease.[6] We found no reliable data about age or sex distribution of physiological halitosis.

AETIOLOGY/ RISK FACTORS We found n spectromet of people w volatile sul and dimeth

PROGNOSIS We found n

Please refer to clinicale

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n people with

hwash (one mouthwash containing
is zinc lactate, the other mouthwash
reath odour at 2–4 weeks compared

only)
iat single-use mouthwash reduced
ween 1–8 hours after use compared
RCTs found no significant difference
l water in odour unpleasantness or

ie effects of artificial saliva.

e effects of sugar-free chewing gum.

leaning, brushing, or scraping.

ie effects of zinc toothpaste.

ted from the mouth. It may be caused by
giene, oral and periodontal disease,[1,2] or
s, tonsillitis and bronchiectasis. In this
al halitosis, that is, confirmed persistent
ic, oral or periodontal, disease. We have
systemic disease, which would require
alitosis (in people who believe they have
considered malodourous by others), and
tudies requiring people to stop brushing
able, therefore, to people in whom such
out, and in whom pseudo-halitosis has
us regarding duration of bad breath for
tandard organoleptic test for bad breath
ast two or three different days.[1]

valence, although several studies report
s (physiological or because of underlying
e cross-sectional study of 491 people
alitosis have pseudo-halitosis and about
physiological bad breath not due to
able data about age or sex distribution of

Halitosis

AETIOLOGY/ RISK FACTORS We found no reliable data about risk factors for physiological bad breath. Mass spectrometric and gas chromatographic analysis of expelled air from the mouth of people with any type of halitosis have shown that the main malodourants are volatile sulphur compounds including hydrogen sulphide, methyl mercaptan, and dimethyl suphide.[7,8]

PROGNOSIS We found no evidence on the prognosis of halitosis.

Please refer to clinicalevidence.com for full text and references.